UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/467,901	12/21/99	NEERVEN J	02405.0190

EXAMINER	
DO, P	
ART UNIT	PAPER NUMBER
1641	5

HM12/0301

FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER L L P
1300 I STREET N W
WASHINGTON DC 20005-3315

DATE MAILED: 03/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/467,901	Neerven, Joost Van
Examiner	**Group Art Unit**
Pensee T. Do	1641

☒ Responsive to communication(s) filed on *Mar 21, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-22* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-22* is/are rejected.

☒ Claim(s) *10-16, 21, and 22* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on March 21, 2000 has been acknowledged and entered as paper no. 4.

Specification

2. The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 10-16, 21 and 22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 10-16, 21 and 22 have not been further treated on the merits.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Labeling the complexes after separation or using the solid support as a detectable means for "determining the amount of the carrier-bound IgE containing complexes formed" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled

by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claim 1 either lacks a label to "determine the amount of the carrier-bound IgE-containing complexes formed" or a detectable solid support (carrier) in order to quantify the amount of IgE in the sample.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Since the label compound is bound to avidin, streptavidin or a functional derivative thereof, labeling a component of the assay with or adding a biotin is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). It is well known in the art that in order to detect avidin-bound labels, biotin must be present to catalyze the signal. However, the method of claim 8 lacks a biotin or biotinylation step.

7. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites in step (c) "a mixture II comprising **carrier-bound IgE-containing complexes**" and subsequently in step (d) "separating the **carrier-bound IgE-containing complexes** from the mixture II". Since mixture II contains no other components besides the carrier-bound IgE-containing complexes, what is there to be separated from mixture II ? Therefore, separation is not enabled.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For all dependent claims, please change "A" in line one before "method" to --The-- for proper antecedent basis.

Claim 1 is indefinite and confusing in reciting in lines 6-7 "to form a mixture I comprising IgE-containing complexes. First, "IgE" is not specified as an antibody or an antigen. Second, the sample is not specified as to be suspected of containing an IgE antibody/antigen. Third, the complex is not clearly recited to comprise an IgE antibody/antigen and the ligand. (See also IgE-containing complexes" in lines 10-11).

In claim 1, please insert --the-- or --said-- before "mixture I" in line 8 for proper antecedent support. "IgE receptor" in line 9 lacks antecedent support.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "IgE receptor" in line 9, and the claim also recites "said IgE receptor being CD23 " which is the narrower statement of the range/limitation. See also claim 20 for the same problems.

Claim 1 is confusing in step (c). Since "mixture II" is recited as to "comprising carrier-bound IgE-containing complexes", how can "the carrier-bound IgE-containing complexes" be separated, as recited in step (c), "from mixture II" ?

In claim 7, "mixture II' " in line 3 lacks antecedent support.

In claim 19, please add an open parentheses --(-- to " c)".

In claim 20, "mixture II" in step (b) lacks antecedent support.

Claim 17 is indefinite because the step of "using a detection system ..." is not recited in any sequential order, e.g. after step (c) , step (b) etc. in claim 1.

Claim 19 is confusing because the carrier-bound complexes formed in step (b), not (c).

11. Claims 21-22 provide for the use of the method, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending

to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 21-22 do not recite any steps for monitoring and evaluating the immunological status of a subject or a subject receiving Specific Allergy Vaccination (SAV) treatment.

Claims 21-22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

13. Claims 1-14, 16, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Johansen et al. (US 6,087,188).

Johansen et al. teach a method of detecting an antibody in a sample using a labeling compound and comprising the steps of mixing the ligand antigen, antibody or hapten bound to biotin with the sample; an antibody is directed against the antibody to be detected bound to a

paramagnetic particles; and a chemiluminescent acridinium compound bound to avidin or streptavidin to form a solid phase complex; separating the solid phase from the liquid phase; and analyzing the separated solid phase for the presence of chemiluminescent complex. There are several embodiments. In one embodiment, the method comprises the following steps: mixing the ligand antigen, antibody or hapten bound to biotin or a functional derivative thereof with the samole and the antibody directed against the antibody to be detected bound to paramagnetic particles to form a first solid phase complex; adding a chemiluminescent acridinium compound covalently bound to avidin, streptavidin or a functional derivative thereof to form a second solid phase complex; magnetically separating the solid phase from the liquid phase; initiating the chemiluminescent reaction, and analyzing the separated solid phase for the presence of the chemiluminescent complex. Johansen et al. also teaches the method for the quantification of specific antibodies, such as immunoglobulins, wherein a truly parallel reference immunoassay using an identical protocol as a reference. The method comprises measuring the concentration and/or the relative contents of a specific antibody in a liquid sample, wherein the measured light emission of a separated solid phase comprising a captured specific antibody coupled to a chemiluminescent label is compared with the measured light emission obtained in a parallel reference immunoassay wherein the total contents of the class of antibodies in the sample to which said specific antibody belongs is measured. The method comprising the steps of mixing a ligand antigen, hapten towards which the specific antibody to be measured is directly bound to biotin or a functional derivative thereof; an antibody directed against the constant portion of the antibody

to be measured bound to paramagnetic particles and a chemiluminescent acridinium compound bound to avidin, streptavidin or a functional derivative thereof with the sample to form a first solid phase from the liquid phase; magnetically separating the first solid phase from the liquid phase; initiating a chemiluminescent reaction and measuring the light emission of the separated first solid phase; mixing a ligand antibody directed against the class of antibodies to be measured bound to biotin or a functional derivative thereof; an antibody directed against the constant portion of the class of antibodies to be measured bound to paramagnetic particles ; and a chemiluminescent acridinium compound bound to avidin, streptavidin or a functional derivative thereof wherein the term total shall mean the entire amount of the designated class of immunoglobulins (e.g. IgA, IgE, etc.) With the sample to form a second solid phase complex, magnetically separate the second solid phase form the liquid phase; initiating the light emission of the separated first solid phase with that of the separated second solid phase. The specific antibody to be measured in the sample is preferably a specific immunoglobulin selected from the group consisting of IgA, IgD, IgE, IgG, IgM and subclasses thereof. (See col. 3, line 30-col. 5, line 45).

14. Claims 1, 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Frank et al. (US 5,945,294).

Frank et al. teach a method for detecting IgE comprising using a FcϵR as a capture molecule by being immobilized on a substrate, such as a microtiter dish well or a dipstick. A biological sample collected from an animal is applied to a substrate and incubated under conditions suitable to allow for FcϵR molecule:IgE complex binding to the substrate . An

indicator molecule that can selectively bind to an IgE bound to the FcεR is added to the substrate and incubated to allow formation of a complex between the indicator molecule and the FcεR molecule:IgE complex. Preferably the indicator molecule is conjugated to a detectable marker (such as a biotin). Excess labels is removed. A developing agent is added. (See col. 12, lines 3-53).

Claim Rejections - 35 U.S.C. § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen et al. (US 6,087,188) further in view of Johnson et al. (US 6,034,066) and Frank et al. (US 6,060,326).

Johansen et al. has been discussed earlier.

However, Johansen et al. do not teach a method of quantification of IgE wherein the IgE to be detected is quantified using both CD23 alone to obtain a first measurement and using FcεRII alone to obtain a second measurement.

Johnson et al. teach multiple important roles of CD23 in the regulation of immune responses, particularly the regulation of IgE responses. Among these roles, CD23 acts as a cellular receptor for IgE and is found in various cell types including B cells. (See col. 1, line 31-col. 2, line 64).

Frank et al. teach detecting IgE antibodies using a human Fc epsilon receptor FcεR. (See col. 1, line 45-col. 2, line 10).

It would have been obvious to one of ordinary skill in the art to use the IgE receptors of Johnson et al. and Frank et al. to measure IgE according to the method of Johansen et al. since both of these receptors, CD23 and FcεR, are specific to IgE antibody and because FcεR and CD23 can bind to IgE with less isotype cross-reactivity and more sensitivity than anti-IgE biding antibodies. (See Frank et al. Col. 1, lines 19-34).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 7 a.m. to 3 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do
Patent Examiner
February 16, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/26/01